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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,330	10/22/2003	Istvan Boldogh	265.00390101	1384

26813 7590 06/08/2006

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 06/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/691,330

Applicant(s)

BOLDOGH ET AL.

Examiner

Chih-Min Kam

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.  
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6,8 and 12-15 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-6,8 and 12-15 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 22 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/20/06.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-6, 8 and 12-15 are pending.

Applicants' amendment and Declaration of Attorney Nancy Johnson filed March 20, 2006 are acknowledged. Applicants' response and Declaration of Nancy Johnson have been fully considered. Claim 1 has been amended, and claims 7 and 9-11 have been cancelled. Therefore, claims 1-6, 8 and 12-15 are examined.

### **Withdrawn Informalities**

2. The previous objection to the specification is withdrawn in view of applicants' amendment to the claim, and applicant's response at page 7 in the amendment filed March 20, 2006.

### **Withdrawn Claim Rejections - 35 USC § 112**

3. The previous rejection of claims 7 and 9-11, under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' cancellation of the claim, and applicants' response at page 8 in the amendment filed March 20, 2006.

### **Withdrawn Claim Rejections - 35 USC § 102**

4. The previous rejection of claims 1-15, under 35 U.S.C. 102(e) as anticipated by Stanton *et al.* (U.S. Patent 6,903,068, filing date: August 17, 2000), is withdrawn in view of Declaration of Attorney Nancy Johnson and Exhibit A (documents related to Application No. 09/641,801), applicants' cancellation of the claim, and applicants' response at page 8 in the amendment filed March 20, 2006.

Art Unit: 1656

U.S. Patent 6,903,068 (U.S. Patent Application No. 09/641,801) as published on June 7, 2005 has erroneous specification as compared to the specification of Application No. 09/641,801 as shown in the Declaration of Attorney Nancy Johnson and Exhibit A, and the published U.S. Patent 6,903,068 has the specification of Application No. 10/691,157, which has an effective filing date of 10/23/03 that is later than the effective filing date of instant application (10/22/03). Therefore, the rejection is withdrawn.

***New Claim Rejections-Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-6, 8 and 12-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U. S. Patent 6,500,798. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-6, 8 and 12-15 in the instant application disclose a method for inhibiting apoptosis or a method for protecting against DNA damage in a cell, the method comprising contacting the cell with an apoptosis inhibitor selected from the group consisting of colostrinin, a constituent peptide of colostrinin (SEQ ID NO:1-8) and combination thereof, and the specification indicates UV-irradiation is a major cause of oxidative stress in the cells and may induce apoptosis

Art Unit: 1656

(Example 8; pages 28-29). This is obvious in view of claims 1-8 of the patent which disclose a method for modulating the oxidative stress level in a cell, the method comprising contacting the cell with an oxidative stress regulator under conditions effective to decrease the level of an oxidizing species in the cell in response to an oxidative stress, wherein the oxidative stress regulator is colostrinin, a constituent peptide of colostrinin (SEQ ID NO:1-34), an active analog of a constituent peptide of colostrinin (SEQ ID NO:1-34) and combination thereof. Both sets of claims are directed to a method for inhibiting apoptosis or a method for modulating the oxidative stress level in a cell by contacting the cell with an effective amount of colostrinin, a constituent peptide of colostrinin and combination thereof in response to apoptosis or an oxidative stress such as UV-irradiation. Therefore, claims 1-6, 8 and 12-15 in instant application and claims 1-8 of the patent are obvious variations of a method for inhibiting apoptosis or a method for modulating the oxidative stress level in a cell by contacting the cell with an effective amount of colostrinin, a constituent peptide of colostrinin and combination thereof in response to apoptosis or an oxidative stress.

6. Claims 1-6, 8 and 12-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U. S. Patent 6,903,068.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-6, 8 and 12-15 in the instant application disclose a method for inhibiting apoptosis or a method for protecting against DNA damage in a cell, the method comprising contacting the cell with an apoptosis inhibitor selected from the group consisting of colostrinin, a constituent peptide of colostrinin (SEQ ID NO:1-8) and combination thereof, and the specification indicates colostrinin induces a variety of cytokines in leukocytes or modulates

Art Unit: 1656

cytokine production (page 8, lines 11-15; page 22, lines 32-33; page 29, lines 24-30). This is obvious in view of claims 1-10 of the patent which disclose a method for inducing a cytokine or a method for modulating an immune response in a cell, the method comprising contacting the cell with an immunological regulator under conditions effective to induce a cytokine, wherein the immunological regulator is colostrinin, a constituent peptide of colostrinin (SEQ ID NO:1-8 and 34), an active analog of a constituent peptide of colostrinin (SEQ ID NO:1-8 and 34) and combination thereof. Both sets of claims are directed to a method for inhibiting apoptosis or a method for inducing a cytokine in a cell by contacting the cell with an effective amount of colostrinin, a constituent peptide of colostrinin and combination thereof. Therefore, claims 1-6, 8 and 12-15 in instant application and claims 1-10 of the patent are obvious variations of a method for inhibiting apoptosis or a method for inducing a cytokine in a cell by contacting the cell with an effective amount of colostrinin, a constituent peptide of colostrinin and combination thereof.

7. Claims 1-6, 8 and 12-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of co-pending application 10/691,157 (based on allowable claims filed April 25, 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-6, 8 and 12-15 in the instant application disclose a method for inhibiting apoptosis or a method for protecting against DNA damage in a cell, the method comprising contacting the cell with an apoptosis inhibitor selected from the group consisting of colostrinin, a constituent peptide of colostrinin (SEQ ID NO:1-8) and combination thereof, and the specification indicates 4-HNE (4-hydroxynonenal) induce apoptosis (Example 7; page 28). This is obvious in view of

Art Unit: 1656

claims 1-7 of the patent which disclose a method for modulating an intracellular signaling molecule in a cell such as reducing 4-hydroxynonenal (4HNE)-protein adduct formation, inhibiting 4HNE-mediated glutathione depleting, inhibiting 4HNE-induced activation of p53 protein, inhibiting 4HNE-induced activation of c-Jun NH2-terminal kinases, or a method for down regulating 4HNE-mediated oxidative damage associated with lipid peroxidation in a cell, the method comprising contacting the cell with an effective amount of a regulator, wherein the regulator is colostrinin, a constituent peptide of colostrinin (SEQ ID NO:1-8) and combination thereof. Both sets of claims are directed to a method for inhibiting apoptosis or a method for modulating an intracellular signaling molecule in a cell by contacting the cell with an effective amount of colostrinin, a constituent peptide of colostrinin and combination thereof. Therefore, claims 1-6, 8 and 12-15 in instant application and claims 1-7 of the co-pending application are obvious variations of a method for inhibiting apoptosis or a method for modulating an intracellular signaling molecule in a cell by contacting the cell with an effective amount of colostrinin, a constituent peptide of colostrinin and combination thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusions***

8. No claims are allowed.

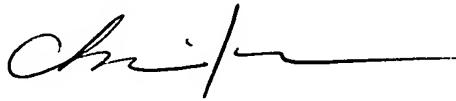
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1656

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner



**CHIH-MIN KAM**  
**PATENT EXAMINER**

CMK

June 5, 2006